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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,703	04/29/1998	GILLES H. TAPOLSKY	VIRO:034	3665

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/24/2003

53

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/064703

Applicant(s)

TAPOLSKY

Examiner

WEBMAN

Group/Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/7/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-10, 12, 13, 15-18, 33, 34 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9, 12, 15, 17-18, 34 is/are rejected.
- ☒ Claim(s) 10, 13, 16, 33 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 12, 15, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Takayanagi et al.

Takayanagi et al teach a medical tape for oral mucosa comprising a support layer and a medical layer composed of a water-soluble polymer (abstract). PVP, sodium polyacrylate, and carboxyl cellulose are specified (column methyl 2 lines 61-64). A second polymer, hydroxypropyl cellulose, is specified (column 3 lines 61-64). The medicament layer may be composed of two or more layers (column 3 lines 18-19). One or more water-soluble polymers are disclosed (column 2 line 68 column 3 line 2). Methylcellulose is specified (column 2 lines 65-66). Dissolution time may be varied by proper selection of polymers (column 3, lines 29-33) anti-inflammatory steroids are disclosed (column 2 lines 48-53). A 200 um thickness is specified (column 3, lines 15-16).

Applicants argue that Takayanagi et al requires plasticizers. Applicants cite column 4 lines 5-11. However, line 5 specifies that softening agents are preferred rather than required. As to the examples all reciting a softener, the teachings in a reference are not limited to its examples.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 12, 15, 17-19, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayanagi et al in view of WO 95/05416 (WO '416) and EPA 250187 (EPA '187).

Takayanagi et al is discussed above.

WO '416 teaches overlaying an adhesive layer to prevent leakage of active from edges (page 30 lines 16-24).

EPA '187 teaches an intra-oral film (Title). Flavors are disclosed as customary (page 4, lines 41-43).

It would have been obvious to one of ordinary skill to overlay an adhesive layer in Takayanagi et al to achieve the beneficial effect of preventing Leakage of active from edges in view of WO '416 and to add a flavor as a customary additive in intra-oral films in view of EPA '187.

Takayanagi et al stands in view of the rebuttal to applicants' arguments above. As to applicants' argument that WO '416 requires plasticizers, WO '416 is cited only for its teaching of overlaying to prevent leakage, a teaching independent of the requirement.

Claims 10, 13, 16, 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd
June 3, 2003

Art Unit: 1617

Page 5

2